



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0194]

Information Collection: Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

DATES: Submit comments by **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2018-0194**. Address questions about docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; email: Jennifer.Borges@nrc.gov.

For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** David Cullison, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2018-0194** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2018-0194**.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The supporting statement and NRC Form 653, 653A and 653B are available in ADAMS under Accession Nos. ML18323A028 and ML19037A053, respectively.

- **NRC’s PDR:** You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville,

Maryland 20852.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Please include Docket ID **NRC-2018-0194** in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Title 10 of the *Code of Federal Regulations* (CFR), Part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.”

2. *OMB approval number:* 3150-0001.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 653, NRC Form 653A, and NRC Form 653B.

5. *How often the collection is required or requested:* There is a one-time submittal of information to receive a certificate of registration for a sealed source and/or device. Certificates of registration for sealed sources and/or devices can be amended at any time. In addition, licensee recordkeeping must be performed on an on-going basis, and reporting of transfer of byproduct material must be reported every calendar year, and in some cases, every calendar quarter.

6. *Who will be required or asked to respond:* All specific licensees who manufacture or initially transfer items containing byproduct material for sale or distribution to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device.

7. *The estimated number of annual responses:* 3,197 [2,637 reporting + 252 recordkeepers + 308 third-party recordkeepers].

8. *The estimated number of annual respondents:* 617 (180 NRC licenses, registration certificate holder, and 437 Agreement States licensees and registration certificate holders).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 66,585 (18,405 reporting + 1,112 recordkeeping + 47,068 third-party).

10. *Abstract:* 10 CFR Part 32, establishes requirements for specific licenses for the introduction of byproduct material into products or materials and transfer of the products or materials to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device. It also prescribes requirements governing holders of the specific licenses. Some of the requirements are for information which must be submitted in an application for a certificate of registration for a sealed source and/or device, records which must be kept, reports which must be submitted, and information which must be forwarded to general licensees and persons exempt from licensing. As mentioned, 10 CFR Part 32 also prescribes requirements for the issuance of certificates of registration (concerning radiation safety information about a product) to manufacturers or initial transferors of sealed sources and devices. Submission or retention of the information is mandatory for persons subject to the 10 CFR Part 32 requirements. The information is used by the NRC to make licensing and other regulatory determinations concerning the use of radioactive byproduct material in products and devices.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 28th day of March 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer,

Office of the Chief Information Officer.

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